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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,510	11/08/2001	Charles S. Schasteen	NVI 5183.1	9657

321 7590 11/04/2005

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,510	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-30,113-116,118,119,136-146,148-150,153 and 154* is/are pending in the application.

4a) Of the above claim(s) *144 and 145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-30, 113-116, 118-119, 136-143, 146, 148-150 and 153-154* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant filed the RCE on August 16, 2005. Applicant's amendments and remarks were filed on April 28, 2005 and have been entered. Claims 1, 4, 9-10, 29, 113, 136-140, 146 and 148 have been amended. Claims 2-3, 31-112, 117, 120-135, 147 and 151-152 have been cancelled. Claims 144-145 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 153-154 have been added.

Rejection Withdrawn

2. In view of Applicant's amendment and remarks the rejection under 35 U.S.C. 112, first paragraph (new matter), pages 11-12, paragraph 5 of the Final Office Action is withdrawn.

For clarification of the record the rejection of claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150 and newly submitted claims 153-154 is maintained under 35 U.S. C. 102(a) and not 35 U.S.C. 102(b).

Rejections Maintained

3. The rejection is maintained for claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and newly submitted claims 153-154 under 35 U.S.C. 102(a) as anticipated by Conkle et al, for the reasons set forth on pages 2-8, paragraph 3 of the Final Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as inherent and as a limitation of intended use. The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or

printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition*. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Conkle et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the

product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that as defined amended claim 1, is directed to novel compositions for prevention or control of coccidiosis. Applicant urges that the composition is not only substantially or entirely free of potassium dichromate but is also substantially free of bacterial contaminants derived from the oocysts source. Applicant teaches that by excluding bacterial contaminants derived from the source of oocysts the composition of the invention is distinguished from the composition of Conkle et al. Applicant urges that Conkle et al teach the treatment of their compositions with antibacterial agents. Applicant urges that it is important to understand that bacterial contaminants as specified in claim 1 encompasses not only live bacteria but non-viable contaminants such as dead bacteria and cellular debris that remain after treatment with an antibacterial agent. Applicant urges that treatment according to Conkle et al may be effective for killing bacteria but Conkle et al fail to teach or suggest removal of non-viable bacteria or bacterial debris whether by tangential flow filtration or otherwise. Applicant urges as specified in claim 1 since the pore size of the filter membrane used during tangential flow filtration is large enough to allow bacteria to pass through the oocysts retained by the filter membrane has been separated from both viable and non-viable contaminants such as bacteria and cellular debris. Applicant urges that the oocysts in the composition of amended claim 1 contain a much lower amount of bacterial contaminants than would be present where the pore size is small enough to

retain bacteria as well as oocysts. As known by those in the art, the presence of contaminants such as non-viable bacterial contaminants in a vaccine composition increases the risk of producing a pyrogenic reaction in vaccinated animals. Applicant urges that compositions of amended claim 1 would reduce the risk of animals having a pyrogenic reaction. Applicant urges that Conkle et al state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level and serial washings maybe conducted preferably by membrane filtration or by diafiltration. Applicant urges that Conkle et al do not disclose the use of a filter pore size small enough to prevent sporulated oocysts from entering the pores but large enough to allow bacteria to pass through the pores. Applicant urges that there is no suggestion of the desirability of separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension. Applicant urges that the composition of Conkle et al have a greater amount of non-viable bacterial contaminants than the claimed composition. Applicant urges that claim 113 is directed to a kit comprising the composition of claim 1 and instructions for administration of the composition to an animal and this claim has been amended. Applicant urges that instructions in the kit constitute more than intended use. Applicant urges that instructions are functionally related to the composition and therefore should be given patentable weight. Applicant urges that "a ratio defined by the minimum immunizing dose" and "amount determined by storage half-life determinations" are more than intended use and it cannot be found inherently in Conkle et al (claim 139).

Applicant's arguments filed April 28, 2005 have been fully considered but they are not persuasive. The claims are directed to composition comprising viable sporulated oocysts (a product). Conkle et al teach compositions comprising sporulated oocysts (see the Abstract). Conkle et al teach that the encysted protozoa which includes cysts and oocysts may be obtained from various sources including purified suspensions, intestinal lings and fecal suspensions (page 4).

It is the Examiner's position that Applicant is arguing process limitations in a product claim. MPEP 2113 discloses that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Therefore, one of skill in the art would reasonably conclude that the patentability of the product is based on the product itself.

To address Applicant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the used of filter membranes with specific pore sizes (which includes the limitations in newly submitted

claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Applicant has provided no side-by-side comparison to show that the claimed compositions differs from that of the prior art.

It should be noted that the Examiner disagrees with Applicant's assertion that " the prior art does not disclose separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension". It should be noted that in this response Applicant admits that "Conkle et al state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level and serial washings maybe conducted preferably by membrane filtration or by diafiltration". See page 16 of Applicant's response and

page 8 of Conkle et al. This process as disclosed by Conkle et al teach the removal of contaminants from the suspension comprising the oocysts.

To address Applicant's comments regarding pyrogenic reactions, it should be noted that the claimed invention is not directed to a method of vaccinating animals by administering the vaccine composition. It should be noted that Applicant is arguing limitations of intended use for the claimed product. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

To address Applicant's comments regarding a kit, it should be noted that the kit as set forth in claim 113 comprises the composition of claim 1 and instructions for the administration of said composition to an animal. It should be noted that the instructions as to how to use the kit is a limitation of intended use and has no functional relatedness to the composition.

To address Applicant's comment's regarding, "... a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" would be inherent in the teachings of the prior art because Conkle et al teach that encysted protozoa oocysts including *Eimeria maxima, E. mitis, E. tenella, E. acevulina, E.*

brumetti, E. necatrix, E. praecox and mixtures thereof including multiple strains can be give in a single vaccine. Vaccines are known as pharmaceutical compositions that are used to immunize subjects and are thereby given in immunizing doses and can include determination by storage half-life determinations. Therefore, this claim limitation is met by the prior art. It is the position of the Examiner that Conkle et al anticipate the claimed composition.

4. The rejection is maintained for claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and newly submitted claims 153-154 under 35 U.S.C. 103(a) as unpatentable over Conkle et al in view of Brown et al for the reasons set forth on pages 9-12, paragraph 9 of the previous Office Action.

The rejection was on the grounds that Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8).

Conkle et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as, "a kit", "the composition ameliorates a decline in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as limitations of intended use. The claims limitation "wherein said composition contains at least about 30 milligrams (dry weight of *P. acnes* per milliliter is being viewed as a limitation of optimizing experimental parameters since Brown et al teach that other initial concentrations of *P. acnes* suspension are within the scope of the invention because the actual administration to the chick is adjusted and diluted for optimum dosages (column 4, lines 19-22). The

claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus *Eimeria* of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Applicant urges that other than the disclosure of *P. acnes* Brown et al adds nothing to the teachings of Conkle et al. Applicant urges that the Examiner has no identified any other teachings of Brown et al that are relevant to the claimed compositions. Applicant urges that they are at a loss to understand the 103 rejection of claims 1, 4-22, 29, 30, 113-116, 118-119, 136-141, 146 or 148-150, since none of these claims have been rejected under 103 on the basis of Conkle et al alone, there would not seem to be any basis on which they could be found obvious from Conkle et al in view of Brown et al. Applicant urges that the claims are patentable over Conkle et

al in view of Brown et al. Applicant urges that there is no motivation to modify the cited references since there is no disclosure or suggestion in the prior art to arrive at a composition comprising oocysts that are substantially free of bacterial contaminants which have been separated by tangential flow filtration having a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but the bacterial contaminants can pass through the pores.

Applicant's arguments filed April 28, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Conkle et al teach compositions comprising oocysts (page 4). Conkle et al do not teach *Propionibacterium acnes*. However, Brown et al teach compositions comprising *P. acnes*. One of ordinary skill in the art would be motivated to add the *P. acnes* compositions as taught by Brown et al to the compositions comprising sporulated oocysts of Conkle et al because Brown et al teach *Propionibacterium acnes* is an immunostimulant for providing non-specific cell-mediated immune response in poultry (column 3). One of ordinary skill in the art would expect a reasonable expectation of success in using the compositions of Brown et al and Conkle et al as combined

because Brown et al teach that *P. acnes* can be used to combat coccidiosis at an age as early as one or even *in ovo* and other poultry diseases and Conkle et al teach that the sporulated oocysts of the invention can be formulated into a vaccine against avian coccidiosis.

The Examiner disagrees with Applicant's assertion that there is no rejection over claims 1, 4-22, 29, 30, 113-116, 118-119, 136-141, 146 or 148-150, it should be noted that the above 102 rejection as anticipated by Conkle et al includes all of these claims. The rejection is made under 35 U.S.C. 102 instead of 35 U.S.C. 103 because the claims are directed to a product and not a process of making the product. It should be remembered that the patentability of the product is based on the product itself.

To address Applicants comments regarding tangential flow and pore size, these limitation are process limitations. It should be remembered that the claims are drawn to product. It should be further remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and newly submitted claims 153-154 are rejected under 35 U.S.C. 102(b) as anticipated by Evans et al *(WO 96/40234, published December 19, 1996).*

Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 are drawn to a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts that are derived from an oocysts source comprising bacterial contamination and comprise at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.4% by weight of alkali metal dichromate said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter pores, but said bacterial contaminants can pass through the pores.

Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach that a typical dose of sporulated oocysts is 200, 000 oocysts/bird (page 5). Evan et al teach that oocysts can of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts(page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as "... said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores "are being viewed as process limitations. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173

USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance", "kit for prevention or control of coccidiosis" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use.

The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition

which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed compositions. The compositions remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the claims are drawn to a composition comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. Evans et al anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and newly submitted claims 153-154 are rejected under 35 U.S.C. 103(a) as unpatentable over Evans et al *(WO 96/40234, published December 19, 1996)* in view of Brown et al *(U.S. Patent No. 6, 019, 985, published February 1, 2000).*

Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and 153-154 are a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts that are derived from an oocysts source comprising bacterial contamination and comprise at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.4% by weight of alkali metal dichromate said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter pores, but said bacterial contaminants can pass through the pores and further comprising *Propionibacterium acnes*.

Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach that a typical dose of sporulated oocysts is 200, 000 oocysts/bird (page 5). Evan et al teach that oocysts can of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts(page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art.

Evans et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as "the composition ameliorates a decline in post-challenge performance", kit for the prevention or control of coccidiosis comprising instructions for administration of said composition to an animal" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as "... said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores "are being viewed as process limitations.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the

coccidiosis vaccines comprising oocysts of Evans et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases and Evans et al teach that vaccine compositions comprising *Eimeria* oocysts are effective at vaccinating poultry against coccidiosis (see the Abstract). It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts and *Propionibacterium acnes* would be effective in preventing coccidiosis in animals.

Status of Claims

7. No claims are allowed.

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
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October 19, 2005

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